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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,657	01/24/2001	Francisco Cabrera	Mo-6151/MD-96-6	3791

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,657	CABRERA, FRANCISCO	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 20 November 2003.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Receipt of the Amendment and Response filed 11/20/03 is acknowledged.

The 35 U.S.C. §102(b) rejection of Vetter has been *withdrawn*.

Claims 1-8 are pending. Claims 1-8 remain rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vetter *et al.* (US Pat. No. 5,808,076).

Vetter teaches solid oral preparations of micronized quinolone- or naphthyridonecarboxylic acids for use in feed formulations that mask bitter flavoring and fight bacterial infections in humans and animals (see reference column 1, lines 1-45); (column 2, lines 44-58); (column 3, lines 50-65); (column 5, lines 19-35) and claims. The preparation also contains polyvinyl alcohols, polyethylene glycols and the like (col. 2, lines 49-58).

The instant claims are drawn to a solid phase dispersion comprising micronized quinolonecarboxylic acid or micronized naphthyridonecarboxylic acids in an insoluble matrix.

Vetter teaches at col. 3, lines 63-65, that if small particles are required, micronizing may be an option, for example by using an air impact, bead or trituration mill. Vetter also teaches sieving, grinding and granulation of particles at col. 3, lines 57-62. This meets the requirements of the instant generic claims, which require micronized quinolonecarboxylic acid or micronized naphthyridonecarboxylic acids, since Vetter teaches the option of micronizing to obtain smaller-sized particles. Furthermore, it would have been obvious to one of ordinary skill in the pharmaceutical art to conduct micronization of particles, if smaller particle sizes were desired, as this is routinely or conventionally practiced in the art.

Claims 1-2 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lange et al. (US Pat. No. 5,152,986) in view of Vetter et al. (US Pat. No. 5,808,876).

Lange teaches a solid oral preparation comprising quinolone- or naphthyridonecarboxylic acids, polyethylene glycols and polyvinyl alcohols for use in feed formulations, which mask bitter taste, improve the animal's intake and consumption of the feed formulation and fight bacterial infections in humans and animals (see reference column1, lines 1-11); (column 2, lines 48-66); (column 3, lines 36-47); (column 5, lines 10-32); (column 6, lines 19-26, 52-66); (column 11, lines 21-52); (column 12, lines 1-31).

Lange are deficient only in the sense that he does not explicitly teach micronized quinolone- or micronized naphthyridonecarboxylic acids.

Vetter teaches solid oral preparations of quinolone- or naphthyridonecarboxylic acids wherein the particles may be micronized form if small particles are required, for example by using an air impact, bead or trituration mill (col. 3, lines 63-65). Vetter also teaches sieving, grinding and granulation of particles at col. 3, lines 57-62.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the micronized quinolone- or micronized naphthyridonecarboxylic acids of Vetter within the solid preparation of Lange because Vetter teaches that micronizing may be an option if smaller particles are desired and similarly Lange teaches quinolone- or naphthyridonecarboxylic acids wherein as

demonstrated in Example 7, the active substances are *comminuted* through a grater, dried and then sieved to the *desired particle size* (see col. 8, lines 11-27). The expected result would be an improved, micronized quinolone- or micronized naphthyridonecarboxylic acids solid formulation for use in animal feed.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lange et al. (US Pat. No. 5,152,986) *or* Vetter et al. (US Pat. No. 5,808,876) in view of Pollinger *et al.* (US Pat. No. 5,695,784).

As discussed above, *Lange* teaches a solid oral preparation comprising quinolone- or naphthyridonecarboxylic acids, polyethylene glycols and polyvinyl alcohols for use in feed formulations, which mask bitter taste, improve the animal's intake and consumption of the feed formulation and fight bacterial infections in humans and animals (see reference column1, lines 1-11); (column 2, lines 48-66); (column 3, lines 36-47); (column 5, lines 10-32); (column 6, lines 19-26, 52-66); (column 11, lines 21-52); (column 12, lines 1-31).

Vetter teaches a solid, homogeneously dispersed oral preparation comprising micronized quinolone- or micronized naphthyridonecarboxylic acids, polyethylene glycols and polyvinyl alcohols for use with taste-sensitive animals for the treatment of bacterial infections (see reference column 1, lines 1-45); (column 2, lines 44-58); (column 3, lines 50-65); (column 5, lines 19-35); and claims.

Lange or Vetter are lacking only in the teachings of shellac in the quinolonecarboxylic acid formulation. It is well within the skill of the pharmaceutical art that various binders and film-forming agents can be implemented, in combination, to increase the mechanical stability and strength of oral preparations. Such skill is also evident from the reference of Pollinger et al. (see below).

Pollinger teaches flavor-masked pharmaceutical compositions comprising naphthyridone- and quinolone-carboxylic acid in combination with shellac, polyethylene glycol and polyvinyl alcohol for example (see reference column 1, lines 30-67); (column 4, lines 9-59); (column 5, lines 7-15, 45-53).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use shellac in combination with quinolone- or naphthyridonecarboxylic acids to mask ill-flavored compositions in feed or foodstuff applications because Pollinger teaches shellac as a suitable ingredient in the naphthyridone- and quinolone-carboxylic acid formulation and similarly, Lange and Vetter teach naphthyridone- and quinolone-carboxylic acid preparations for use in animal feed to mask ill-flavored tastes. The expected result would be an improved tasting, therapeutic composition for the treatment of bacterial infections in humans and animals.

Lange or Vetter do not teach the instantly claimed ratios. However, in the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art

that suitable ranges could be obtained through routine or manipulative experimentation, as these are viewed as variable parameters, in order to obtain the best possible results.

Response to Arguments

Applicant's arguments filed 11/20/03 have been fully considered and were found to be persuasive with regards to the 35 USC 102(b) rejections over Vetter et al.

The applicant argued in regards to the 35 USC 102(b) rejections of Vettter et al. stating, "Vetter et al. discloses preparation of a formulation of quinolonecarboxylic acid or naphthyridonecarboxylic acid and emboniec acid. However, Vetter et al., does not teach or disclose micronized quinolonecarboxylic acid nor micronized naphthyridonecarboxylic acid where the particle size of the solid phase dispersion is about 20 to about 100 mesh size."

This argument has been fully considered and was found to be persuasive in view of the Amendment. Accordingly, the 35 U.S.C. 102(b) rejections over Vetter et al. have been withdrawn.

Secondly, the Applicant argued regarding the rejection of Claims 1-2 and 6-8 under 35 U.S.C. 103(a) over Vetter et al. stating, "Vetter et al. do not teach or suggest micronized quinolonecarboxylic acid nor micronized naphthyridonecarboxylic acid where the particle size of the solid phase dispersion is about 20 to about 100 mesh size. One skilled in the art would not have been motivated to prepare a solid phase dispersion in which the particle size is about 20 to about 100 mesh."

These arguments have been fully considered but they are not found to be persuasive. Vetter et al. teach oral preparations of micronized quinolone- or naphthyridonecarboxylic acids for use in feed formulations that mask bitter flavoring and fight bacterial infections in humans and animals. Although Vetter does not teach the claimed particle size (~ 20 - ~ 100 mesh), Vetter teaches at col. 3, lines 63-65, that if small particles are required, micronizing may be an option, for example by using an air impact, bead or trituration mill. Vetter also teaches sieving, grinding and granulation of particles at col. 3, lines 57-62. Furthermore, it is the position of the Examiner that one of ordinary skill in the art would be capable of determining suitable ranges through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters. Moreover, no unexpected results accrue with the use of the instantly claimed particle size. The prior art clearly teaches and exemplifies solid oral preparations of quinolone- or naphthyridonecarboxylic acids that can be micronized to obtain smaller particles for use in feed formulations. Hence, the arguments are not persuasive.

Next, the Applicant argued regarding the rejection of Claims 1, 2 and 6-8 under 35 U.S.C. §103(a) over Lange et al. ('986) in view of Vetter et al. ('076) stating, "The Examiner acknowledges that Lange et al. do not teach micronized quinolonecarboxlic acid or micronized naphthyridonecarboxylic acid. In addition, Lange et al. do not teach or suggest a solid phase dispersion in which the particle size is about 20 to about 100 mesh size. Vetter does not remedy the deficiencies of Lange. Vetter et al. do not teach or suggest micronized quinolonecarboxylic acid nor micronized naphthyridonecarboxylic acid where the particle size of the solid phase dispersion is about 20 to about 100 mesh size. Thus, based on the disclosures

of Lange et al. and Vetter et al., one skilled in the art would not have been motivated to prepare a solid phase dispersion in which the particle size is about 20 to about 100 mesh size. Since the combination of references does not teach every element of the claimed invention, these references cannot be combined to support a rejection of the claims under U.S.C. §103(a)."

These arguments have been fully considered but they are not found to be persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Lange teaches a solid oral preparation comprising quinolone- or naphthyridonecarboxylic acids, polyethylene glycols and polyvinyl alcohols for use in feed formulations, which mask bitter taste, improve the animal's intake and consumption of the feed formulation and fight bacterial infections in humans and animals. Lange does not explicitly teach micronized quinolone- or micronized naphthyridonecarboxylic acids. However, Lange, in Example 7, demonstrates that the active substances are *comminuted* through a grater, dried and then sieved to the *desired particle size* (see col. 8, lines 11-27). Moreover, Vetter et al. was relied upon for the teaching of solid oral preparations of quinolone- or naphthyridonecarboxylic acids wherein the particles may be micronized form if small particles are required, for example by using an air impact, bead or trituration mill (col. 3, lines 63-65). Vetter also teaches sieving, grinding and granulation

of particles at col. 3, lines 57-62. Therefore ample motivation is provided by the prior art to employ micronized preparations of quinolone- or naphthyridonecarboxylic acids. The argument that neither reference teaches a solid phase dispersion in which the particle size is about 20 to about 100 mesh size has been considered but was not persuasive since one of ordinary skill familiar with this art would be capable of determining suitable particle sizes based on routine experimentation to obtain the best possible outcome, since these are variable parameters. Furthermore, the prior art clearly teaches the generic concept of employing micronized quinolone- or naphthyridonecarboxylic acids for use in animal feed as similarly desired by the Applicants.

Lastly, the Applicants argued regarding the rejection of Claims 3-5 under 35 U.S.C. §103(a) over Lange et al. ('986) or Vetter et al. ('076) in view of Pollinger et al. ('784) stating, "As discussed above, Lange et al. and Vetter et al. do not teach or suggest micronized quinolonecarboxylic acid nor naphthyridonecarboxylic acid, nor a solid phase dispersion having a particle size of about 20 to about 100 mesh. Pollinger et al. also do not teach or suggest micronized quinolonecarboxylic acid nor naphthyridonecarboxylic acid, nor a solid phase dispersion having a particle size of about 20 to about 100 mesh. Thus, based on the disclosure of Pollinger et al., one would not be motivated to prepare the solid phase dispersion as claimed in the present invention. Since the combination of references does not teach every element of the claimed invention, these references cannot be combined to support a rejection of the claims under U.S.C. §103(a)."

These arguments have been fully considered but they are not found to be persuasive. The teachings of Vetter et al. and Lange et al. have been delineated above. Pollinger et al. teach flavor-masked pharmaceutical compositions comprising

naphthyridone- and quinolone-carboxylic acid in combination with shellac, polyethylene glycol and polyvinyl alcohol, for example. Pollinger et al. was relied upon for the generic teaching of the use of shellacs in flavor-masking compositions containing quinolonecarboxylic acid or napthyridonecarboxylic acid. The Applicants argument that none of the references teaches or suggests micronized quinolonecarboxylic acid nor micronized naphthyridonecarboxylic acid with a solid phase dispersion having a particle size of about 20 to about 100 mesh is not persuasive, since as noted above, one of ordinary skill in the art would determine suitable particle sizes through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters. No criticality has been established with the instant particle sizes claimed. The prior art teaches and suggests formulating small particle sizes obtained through grinding, sieving and micronizing. Furthermore, the prior art clearly teaches and exemplifies formulations comprising micronized quinolonecarboxylic acid or naphthyridonecarboxylic acids, polyethylene glycols and polyvinyl alcohols for use in feed formulations. The prior art teaches formulations employing similar ingredients with a similar intended purpose as the Applicants. Hence, the instant claims are rendered obvious and unpatentable over the prior art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
January 29, 2004

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615